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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,275	07/24/2003	Ernest J. Lee	PC28017	9606

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
01/05/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSNY@Pfizer.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/626,275	**Applicant(s)** LEE ET AL.	
	Examiner Nathan W. Schlientz	**Art Unit** 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 December 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires *5* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: ____.
   Claim(s) withdrawn from consideration: ____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/John Pak/
Primary Examiner, Art Unit 1616

Continuation of 11. does NOT place the application in condition for allowance because:
Claims 1, 3-10, 12-15, 20, 24, 25 and 28-41 are rejected under 35 U.S.C. 112, second paragraph, for the reasons of record in the previous Office action.
Applicant argues that the usage of the terms "about", "strongly indicative" and "not so indicative" clearly demonstrate that the numerical end points used should not be considered absolute end points and that some variability must be allowed, to account for the fact that we are dealing in the end, with the effects on a biological system in which absolute predictability is not possible. However, the examiner respectfully argues that the term "about" is not indefinite per se, but rather the terms “no more than about”, “greater than about”, “at least about” and “not greater than about” render the claims indefinite. One of ordinary skill in the art would not be apprised of the scope of the invention because they would not be able to determine where the appropriate ranges begin and end.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, for the reasons of record in the previous Office action.
Applicant's arguments are the same as above. Therefore, the examiner's comments above are incorporated herein by reference.

Claims 1, 3-10, 12-15, 20, 24, 25 and 28-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875) in view of Pospisilik ‘240 (US 2002/0103240) and Vandecruys et al. (WO 00/59477) (cited in the IDS filed 29 April 2004), for the reasons of record in the previous Office action.
Applicant argues that Holman is directed to an immediate release pramipexole formulation, and Pospisilik is directed to a process for resolving pramipexole into enamiomers with only a very brief, general description of fomulating sustained release dosage forms and no disclosure or suggestion of the specific combination of components or the release profile as instantly claimed. Applicant further argues that a careful reading of Vandecruys as a whole shows that (1) there is a high level of unpredictability in modifying the types or amounts of ingredients in controlled release dosage forms; (2) a slight increase in the amount of starch generally results in a significant increase in the release rate; and (3) the reference as a whole teaches away from significantly increasing the amount of starch while also maintaining the controlled release profile relied upon by the Examiner (and shown in Table 5).
The examiner respectfully disagrees that Holman teaches immediate release formulations. Holman teaches a composition comprising PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE, lactose hydrous, PREGELATINIZED STARCH, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, purified water, carnauba wax, HYDROXYPROPYL METHYLCELLULOSE, titanium dioxide, polyethylene glycol, synthetic iron oxide, and polysorbate 80. Holman teaches treating patients with pramipexole at a dose of 0.125 mg once per day at bedtime (qhs) followed by gradually increasing the active on a weekly basis until the patient exhibits a therapeutic effect or intolerance. Holman teaches administering pramipexole at up to 6.0 mg qhs, wherein the effective dose of pramipexole is usually between about 0.125 mg qhs to about 15.0 mg qhs, more usually between about 0.25 mg qhs and about 6.0 mg qhs. Therefore, the composition of Holman comprises pramipexole, a starch (pregelatinized starch), and a hydrophilic polymer (HPMC), and the composition is given to patients once daily.
Also the examiner respectfully argues that Pospisilik clearly teaches motivation to prepare controlled release pramipexole formulations by stating that they may be produced by the process of their invention, and microcrystalline cellulose could be used as a suitable filler and acrylate polymers or modified cellulose could be used as a suitable release controlling polymer. Therefore, Pospisilik provides motivation and some direction as to how to produce controlled release formulations of pramipexole.
With regard to the teaching of Vandecruys, they clearly teach that one of ordinary skill in the art could formulate a controlled release formulation using pregelatinized starch and hydrophilic polymers, such as HPMC, as instantly claimed. Vandecruys teach that the amount of active can vary from 0.01 to 50% (w/w), the amount of starch can vary from 0.01 to <80% (w/w), and the amount of hydrophilic polymer can vary from 0.01 to 80% (w/w) (pg. 20, ln. 21-31). Therefore, one of ordinary skill in the art would have a reasonable expectation of success in formulating a controlled release formulation comprising an active ingredient, starch and hydrophilic polymer according to Vandecruys.

Claims 1, 3-10, 12-15, 20, 24, 25 and 28-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pospisilik ‘240 (US 2002/0103240) in view of Vandecruys et al. (WO 00/59477), for the reasons of record in the previous Office action.
Applicant's arguments are the same as above. Therefore, the examiner's response above is incorporated herein by reference.

Claims 1, 3-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pospisilik ‘119 (US 2004/0068119) in view of Vandecruys et al. (WO 00/59477), for the reasons of record in the previous Office action.
Applicant's arguments are the same as above. Therefore, the examiner's response above is incorporated herein by reference.